



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,617	03/15/2001	Paul O. Sheppard	98-29D1	6610

7590

01/12/2005

Robyn Adams
Patent Department
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/809,617

Applicant(s)

SHEPPARD ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,18-23,36,38,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12,18-23,36 and 41 is/are allowed.
- 6) ☒ Claim(s) 11,38 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on April 2, 2004), Applicants filed a response and amendment received on October 5, 2004. Said amendment amended Claims 11, 12, 18, 20, 36, 38, 40, and 41. Thus, Claims 11, 12, 18-23, 36, 38, and 40-41 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/092,371 filed on July 10, 1998 and U.S. non-Provisional Application No. 09/351,414 filed on July 9, 1999 (the divisional parent application).

Information Disclosure Statement

3. A copy of Hochuli *et al.* has been supplied and is now a part of the record by means of the Examiner's PTO-892 attached hereto.

Withdrawn - Claim Objections

4. Previous objection to Claim 19 for depending from a rejected claim is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claim 38 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's amendment.

Art Unit: 1652

6. Previous rejections of Claims 12, 18, 20-23, 36, and 38 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment including a functional limitation of binding an integrin - a function which is disclosed as being governed by the disintegrin domain 383-464 of SEQ ID NO:2.

7. Previous rejection of Claim 38 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment to exact sequence fragment.

Maintained - Claim Rejections - 35 U.S.C. § 112

8. Previous rejection of Claim 11 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that "each rejection has been addressed and overcome"; the Examiner disagrees. While this amendment overcomes the rejection for Claim 12, for example, that is not the case for Claim 11 since the disintegrin portion of the full-length molecule is not required in the limitations of Claim 11 (164-382 of SEQ ID NO:2 is the protease domain). Thus, since the named structure does not govern the claimed function, the claim lacks adequate written description wherein the structure and function must correlate.

9. Previous rejection of Claim 40 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that "each rejection has been

Art Unit: 1652

addressed and overcome”; the Examiner disagrees. Limitations on residues 443, 444, and 445 does not overcome the rejection.

As previously noted,

“The instant specification teaches SEQ ID NO:2, a multi-domain protein (zdint1) comprising at least a protease domain, a disintegrin domain, and a cysteine-rich domain. The art includes few examples of such multi-domain proteins. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other zdint1 genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a zdint1 gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a zdint1 gene as required by the statute (i.e., “make and use”). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its zdint1-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.”

Thus, having 90% identity and three particular residues does not enable the scope of the claimed invention because one of skill in the art would be unable to make the claimed polynucleotides while retaining function.

Withdrawn - Claim Rejections - 35 U.S.C. § 101

10. Previous rejection of Claim 41 under 35 U.S.C. § 101 is withdrawn by virtue of Applicant’s amendment including “isolated” in the claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

11. Previous rejection of Claim 38 under 35 U.S.C. § 102(b) as being anticipated by Sagane *et al.* (August, 1998) is withdrawn by virtue of Applicant’s amendment requiring the exact portion of SEQ ID NO:2.

NEW ISSUES

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 38 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 depends from a cancelled claim. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 40 is rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The combination of E-C-D (positions 443-444-445) and 90% identity to SEQ ID NO:2 is not found in the specification as originally filed. Applicant is required to delete the alleged new matter or to cite clear support (page and line number) in the specification as originally filed.

Summary of Pending Issues

14. The following is a summary of the issues pending in the instant application:
- a) Claim 38 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for depending from a cancelled claim.
 - b) Claim 11 stands rejected under 35 U.S.C. § 112, first paragraph, written description.
 - c) Claim 40 stands rejected under 35 U.S.C. § 112, first paragraph, new matter.
 - d) Claim 40 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Conclusion

15. Claims 11, 38, and 40 are rejected. Claims 12, 18-23, 36, and 41 are allowed. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

December 29, 2004